K110507

JUL 13 2011

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information
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Device Classification

Proprietary Device Name:	D-SPECT™ Cardiac Scanner System
Common name:	Emission Computed Tomography System
Product Code:	KPS (subsequent code LLZ)
Classification Name:	Emission computed tomography system (Subsequent – Picture archiving and communications system
Classification Regulation:	21 CFR §892.1200 (subsequent 21 CFR §892.2050)
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

Spectrum Dynamics: D-SPECT™ Cardiac Scanner System -	K072468
ELGEMS: eNTEGRA workstation –	K003264
ADAC Laboratories: AutoQUANT -	K980715
UltraSPECT: WBR Half Dose -	K080784

Device Description

Spectrum Dynamics' D-SPECT™ Cardiac Scanner System is a SPECT device, which is designed to perform myocardial perfusion imaging. The device is comprised of a detector head, gantry, and patient chair. Device operation is controlled from an acquisition station console. The system is supported by use of data-transfer accessories (RFID tags), which are attached to the patient's wrist, for patient and radiopharmaceutical agent positive identification. The cardiac gamma camera is designed such that there are no external moving parts that surround the patient. Detector modules rotate within the closed detector head. The special scanning geometry and detector technology enable shorter scan times. Additionally, a new revision of software was developed, adding Archiving, Display and Communication capabilities (NEMA standard DICOM protocol) with external processing stations PACS systems. The new software package also features correction of insignificant bugs discovered since last release. The modified D-SPECT™ Cardiac Scanner System include a Processing workstation. The Processing Workstation, which is part of the imaging system, is equipped with software package for Processing, Archiving, Display, Communication and analysis of emission computerized tomography data using tools for imaging and fully automated review and quantification of Cardiac SPECT data including the Cedars Sinai Quantitative Perfusion SPECT (QPS), Quantitative Gated SPECT (QGS) and Quantitative Blood Pool Gated SPECT (QBS) software.

Intended Use of Device

The D-SPECT™ Cardiac Scanner System is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data.
The D-SPECT™ Cardiac Scanner System is primarily intended for cardiac applications.
The D-SPECT™ Cardiac Scanner System supports radionuclides within the energy range of 40 -170 keV.
The D-SPECT™ Cardiac Scanner System supports acquisition and imaging modes such as, but not limited to, SPECT (Single Photon Emission Computed Tomography), Multi-Gated SPECT and is featuring low count rate (low dose) acquisition, with no lose in image quality.
The D-SPECT™ Cardiac Scanner System is intended for Processing, Reporting, Archiving, Display, Communication and analysis of emission computerized tomography data using tools for imaging and fully automated review and quantification of Cardiac SPECT data including Quantitative Perfusion SPECT (QPS), Quantitative Gated SPECT (QGS) and Quantitative Blood Pool Gated SPECT (QBS).

Safety & Effectiveness

The intended use and indications of the submitted modified D-SPECT™ Cardiac Scanner is identical to the legally marked devices: Spectrum Dynamics: D-SPECT™ Cardiac Scanner System (K072468), ELGEMS: eNTEGRA workstation (K003264), ADAC Laboratories: AutoQUANT (K980715) and UltraSPECT: WBR Half Dose (K080784).
Similarity of intended use, indications and technological features demonstrated, therefore, the risks and benefits are comparable to the predicate devices.
We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of modified D-SPECT™ Cardiac Scanner System.

Rational for Substantial Equivalency

Similarities:
The intended use and indications of the proposed modified D-SPECT™ Cardiac Scanner System are similar to the legally marketed predicate devices.
The technology, performance and most of the specifications of the proposed modified D-SPECT™ Cardiac Scanner System are similar to the legally marketed predicate devices
Differences:
The proposed modified system includes wider indications in reference to legally marked D-SPECT™ Cardiac Scanner System (K072468) indication for use that was limited to Cardiac SPECT acquisition and reconstruction.
The proposed System intended use and indications for use are similar to the above mentioned predicate devices (Adding PACS and fully automated review and quantification of Cardiac SPECT data).

Substantial Equivalence Statement

Based on the above, it is Spectrum Dynamics's opinion that the proposed modified D-SPECT™ Cardiac Scanner System is substantially equivalent in terms of design, functional features and safety & effectiveness to the unmodified D-SPECT™ Cardiac Scanner System (K072468) legally marketed device and to the legally marked predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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JUL 13 2011

Re: K110507
Trade/Device Name: D-SPECT™ Cardiac Scanner System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 20, 2011
Received: February 22, 2011

Dear Mr. Sharon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110507

Device Name: D-SPECT™ Cardiac Scanner System

Indications for Use:

The D-SPECT™ Cardiac Scanner and System is an emission computed tomography system intended to detect the location and distribution of gamma ray radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. The D-SPECT™ Cardiac Scanner System includes display equipment, patient and equipment supports, component parts, and accessories.
D-SPECT™ Cardiac Scanner System is primarily intended, but not limited to, cardiac applications.
D-SPECT™ Cardiac Scanner System supports radionuclides within the energy range of 40-170 keV.

The D-SPECT™ Cardiac Scanner System supports acquisition and imaging modes such as, but not limited to, SPECT (Single Photon Emission Computed Tomography), Multi-Gated SPECT and features low count rate (low dose) acquisition, with no lose in image quality.

D-SPECT™ Cardiac Scanner System is intended for Processing, Reporting, Archiving, Display, Communication and analysis of SPECT data, using tools for imaging and fully automated review and quantification of Cardiac SPECT data including Quantitative Perfusion SPECT (QPS), Quantitative Gated SPECT (QGS) and Quantitative Blood Pool Gated SPECT (QBS).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110507